

Osaka, 5 April 2021

**To whom it may concern****LATEX DECLARATION**

We, KANEKA CORPORATION, Japan, being the manufacturer of the following products hereby declare that:

|                                                     |
|-----------------------------------------------------|
| METACROSS® RX PTA Balloon Dilatation Catheter       |
| METACROSS® OTW PTA Balloon Dilatation Catheter      |
| R2P™ METACROSS® RX PTA Balloon Dilatation Catheter  |
| CROSSTELLA® RX PTA Balloon Dilatation Catheter      |
| CROSSTELLA® OTW PTA Balloon Dilatation Catheter     |
| R2P™ CROSSTELLA® RX PTA Balloon Dilatation Catheter |
| CROSPERIO® RX PTA Balloon Dilatation Catheter       |
| CROSPERIO® OTW PTA Balloon Dilatation Catheter      |
| RX TAKERU™ PTCA Balloon Dilatation Catheter         |
| OTW TAKERU™ PTCA Balloon Dilatation Catheter        |
| RX NC TAKERU™ PTCA Balloon Dilatation Catheter      |

- that above mentioned device and its packaging do not contain components made with natural rubber latex.
- that during the production of the above mentioned product no natural rubber (latex), and no natural rubber (latex) containing parts, have intentionally been used.
- that during the manufacturing process of the above mentioned product, no natural rubber (latex) gloves have been worn.
- that the possible presence of ubiquitous traces, of natural rubber (latex), can of course never be totally ruled out.

Sincerely,

Signature:



Name: Kazuaki Sanaka

Title: QMS Management Representative